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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,512	05/02/2005	Maria Rosa Gasco	GASCO ET AL - 1PCT	4539

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EXAMINER	
HUANG, GIGI GEORGIANA	
ART UNIT	PAPER NUMBER
1627	
MAIL DATE	DELIVERY MODE
04/26/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10533512	5/2/2005	GASCO ET AL.	GASCO ET AL - 1PCT

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EXAMINER	
GIGI HUANG	
ART UNIT	**PAPER**
1627	20110422-A

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Commissioner for Patents

The reply filed on February 4, 2011 does not rectify the non-compliant issue regarding the instant claims which were amended on 5/6/2011. As addressed in the previous office action of 8/3/2010, claim 11 was amended on 5/6/2010 to be directed to an invention that is independent or distinct from the invention originally elected and claimed for the following reasons: On 5/6/2011, claim 11 was amended to recite a method of treatment in conjunction with a method of making in the same claim. Specifically, it recited treating particular ophthalmic disease comprising the intravenous or topical ocular administration of a pharmaceutical active incorporated into solid lipidic nanoparticles and with steps utilizing methods of making the solid lipid nanoparticle.

The application had previously been subject to a restriction where unity was broken as lacking novelty between (1) the method for treating of the ophthalmic disease with the solid lipid nanoparticle, (2) the composition comprising the solid lipid nanoparticle, and (3) the method of making the solid lipid nanoparticle.

Applicant had elected the method of treating the condition with the SLN, and not the method of making or the composition.

The amended claims if originally presented would have be subject to the restriction requirement as it is a separate invention as it recites a method of treatment with a method of making and the method of treatment, composition, and method of making had already been restricted as lacking unity on 9/30/2008.

Applicant had previously elected the method of treatment that did not contain a method of making and both the composition and the method of making were withdrawn from examination.

The claims as amended on 5/6/2011 constituted an improper RCE/noncompliant response as the claims would be withdrawn based on the original election, but as stated previously on 8/3/2010, in an effort to advance prosecution for Applicant, the claims were be treated to the extent that as they read on the originally elected method of treatment with the SLN for the ophthalmic conditions as the amendment addresses the particular conditions for treatment, but did not examine the additionally added steps to the methods of making as it would constitute a new group, thereby giving Applicant an opportunity to clarify and rectify the issue, along with the opportunity to modify the claims to be compliant to the originally elected group by Applicant. Applicant has chosen to not to do so. Applicant has not amended the claims to be read upon the originally elected group and argues that the additional restriction is unwarranted which is not persuasive as had the claims been originally presented as addressed above, they would have been subject to the restriction and the presented restriction had broken unity and established the method of making the SLN, the method of treatment with the SLN without the recite method of making, and the composition where separate groups and the current claims would have been a separate group as it is a method of treatment in combination with a method of making. It is noted to Applicant that one of skill in the art to deliver the method of treatment (e.g. ophthalmologist) would not generally be in possession of the materials/machinery to

manufacture the SLN's as written as they are traditionally found in chemical labs and manufacturing centers, rather than physician offices.

Applicant argues and asserts that the recited claims are directed to the elected method and the imposition of the additional restriction is unwarranted citing the amendment filed 7/10/2009. This is fully considered but not persuasive. The amendment of 7/10/2009 which recited a method of treatment with the solid lipidic nanoparticles with similar but not exact process recitations was unclear and was in fact subjected to the 112 2nd indefiniteness rejection on 11/9/2009, and then treated as a product by process recitation as addressed in the 112 2nd rejection of 11/9/2009. The claims were treated as the method of treatment with the product regardless of the process as Applicant did not provided evidence to establish that the particles produced by the process was distinctly different from that in the art and amended the claims to be commensurate in scope with any evidence or finding to give a product by process recitation patentable weight over the art or record. Instead, the claims were amended on 5/6/2011 by Applicant to it's current form where it now recites a method of treatment of certain ophthalmic conditions with the solid lipidic nanoparticles AND a method of making; which is not the elected group. The claims are nonresponsive as they are not to the elected group, the claims where treated only to the extent that as they read on the originally elected method of treatment with the SLN for the ophthalmic conditions as the amendment addresses the particular conditions for treatment, but did not examine the additionally added steps to the methods of making as it would constitute a new group, and giving Applicant has had an opportunity to recify the issue but Applicant has opted not to do so.

As a result, the claims are clearly non-compliant as they are not readable on the elected invention.

Since the above-mentioned reply appears to be bona fide, applicant is given ONE (1) MONTH or THIRTY (30) DAYS from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).
Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENIVASAN PADMANABHAN can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zohreh A Fay/
Primary Examiner, Art Unit 1627